

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

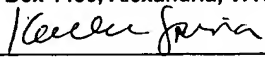
In re:	Patent application of Ajay GUPTA	:	
		:	
		:	Group Art Unit:
Application No.	Not yet assigned	:	Not yet assigned
		:	
Filed:	Herewith	:	Examiner:
		:	Not Yet assigned
For:	METHOD AND PHARMACEUTICAL	:	
	COMPOSITION FOR IRON DELIVERY IN	:	
	HEMODIALYSIS AND PERITONEAL	:	
	DIALYSIS PATIENTS	:	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. § 1.56 and in accordance with 37 C.F.R. §§1.97-1.98,
submitted herewith is a completed substitute Form PTO-1449.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10
EXPRESS MAIL Mailing Label Number: EL998872605US
Date of Deposit: March 9, 2004
<p>I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 CFR 1.10, on the date indicated above, and addressed to: MAIL STOP Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p>
 _____ Signature of person mailing page:
KAREN M. SPINA _____ Type or print name of person

The Examiner is respectfully requested to review the items listed on the attached form and make them of record in the instant application as required by M.P.E.P. §609. It is requested that the Examiner initial the enclosed duplicate substitute PTO Form-1449, and return one copy to the undersigned.

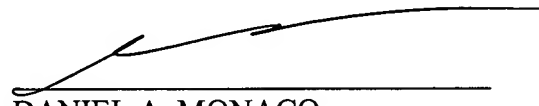
Pursuant to 37 CFR § 1.98(d), copies of the references listed in the substitute Form PTO-1449 are not enclosed, since this patent application is a divisional of U.S. Application No. 09/341,032, filed September 8, 1999. Copies of the references are contained in the file of the earlier application. The Examiner should contact the undersigned if additional copies of any of the listed references are needed.

This Statement should not be construed as a representation that the cited references are material or that more relevant prior art does not exist.

Respectfully submitted,

AJAY GUPTA

BY



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SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE U.S. PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTY. DOCKET NO. 09403-0003 D11	APPLICATION NUMBER Not yet assigned
	FIRST NAMED INVENTOR Ajay GUPTA	
	FILING DATE HEREWITH	ART UNIT Not yet assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	Cite No.	DOCUMENT NUMBER	PUBLICATION DATE (MM/DD/YYYY)	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
		Number-Kind Code (if known)			
	A	3,911,915	10/74	Seifter et al.	
	B	4,315,942	02/82	Corden	
	C	4,756,838	07/88	Veltman	
	D	5,108,767	04/92	Mulchandani et al.	
	E	5,393,777	02/95	Crosa	
	F	5,906,978	05/99	Ash	
	G	4,867,963	09/89	Maurer et al.	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS	Cite No.	FOREIGN PATENT DOCUMENT	PUBLICATION DATE (MM/DD/YYYY)	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	T
		Country Code-Number- Kind Code (if known)				

EXAMINER SIGNATURE		DATE CONSIDERED	
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE U.S. PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTY. DOCKET NO. 09403-0003 DI1	APPLICATION NUMBER Not yet assigned
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NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Publisher, city and/or country where published	T
	H	Sunder-Plassmann et al., <u>Nephrol Dial Transplant</u> , 11:1797-1802 (1996).	
	I	Rubinger et al., <u>Amer. J. Kidney Diseases</u> , VII No. 2:125-129 (1986).	
	J	Zanen et al., <u>Nephrol Dial Transplant</u> , 11:820-824 (1996).	
	K	The Merck Index, Merck and Co., Inc., Rahway, NJ, Budavari Ed., 11 th Edition:3969 (1989).	
	L	<u>Dorland's Illustrated Medical Dictionary</u> , WB Saunders Co., 27 th Edition:462,741,837,1541 (1985).	
	M	Berner et al., <u>J. Nutr.</u> , 115:1042-1049 (1985).	
	N	Hazell et al., <u>Br. J. Nutr.</u> , 39:631-639 (1978).	
	O	Basta, et al., Iron deficiency anemia and the productivity of adult males in Indonesia, <u>Am. J. Clin. Nutr.</u> , 32:916 (1979).	
	P	Brown et al., Intravenously administered saccharated iron oxide in the treatment of hypochromic anemia, <u>JAMA</u> , 144:1084-1089 (1950).	
	Q	Calvar et al., Intravenous administration of iron gluconate during hemodialysis, Iron Research, New York:Plenum Press, 1994:219-228.	
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	R	Cook et al., Iron deficiency: The global perspective, In.:Hershko, C. Ed. Progress in Iron Research, New York: Plenum Press, 1994:219-228.	
	S	Drueke et al., Iron deficiency and erythropoietin in renal anaemia: developing the optimum treatment strategy, In: Highlights Report, The Oxford Forum, Worcester, College, Oxford, 1996. CBC Oxford, Magdalen Centre, The Oxford Science Park, Oxford, UK.	
	T	Fishbane et al., The safety of intravenous iron dextran in Hemodialysis Patients, Am. J. Kidney Dis., 28:529-534 (1996).	
	U	Lieberman et al., Association of maternal hematocrit with premature labor, Am. J. Obstet. Gynecol., 159:107 (1988).	
	V	Lozoff et al., Long-term developmental outcome of infants with iron deficiency, N. Engl. J. Med., 325:687 (1991).	
	W	NKF-DOQI clinical practical guidelines for the treatment of anemia of chronic renal failure, Am. J. Kid. Dis., 30:S192-S137 (1997).	
	X	Ohira et al., Work capacity, heart rate and blood lactate responses to iron treatment, Br. J. Haematol., 41:365 (1979).	
	Y	Oski et al., The effects of therapy on the developmental scores of iron-deficient infants, Pediatrics, 71:877 (1983).	
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	Z	Oski et al., Effect of iron therapy on behavior performance in nonanemic, iron-deficient infants, <u>Pediatrics</u> , 71:877 (1983).	
	AA	Schultink et al., Low compliance with an iron-supplementation program: a study among pregnant women in Jakarta, Indonesia, <u>Am.J. Clin. Nutr.</u> , 32:916 (1979).	
	AB	Stockman, The treatment of chlorosis by iron and some other drugs, <u>Br. Med. J.</u> , I:881-885 (1983).	
	AC	Yoshifumi Tsuji et al., Effect of recombinant human erythropoietin or anamia after gastectomy, <u>Eur. J. Surg.</u> , 161:29-33 (1995).	
	AD	Shimamatsu, Experience with i.v. iron chondroitin-sulphate colloid in Japanese haemodialysis patients, <u>Nephrol Dial Transplant</u> , 13:1053 (1998).	
	AE	The National Formulary VII, 165 (1942).	
	AF	Dainippon Pharmaceutical product description for BLUTAL [®] Injection, 175-177 (1994).	
	AG	Erslev, Drug Therapy, <u>N. Engl. J. Med.</u> , 324 (19):1339-1344 (1991).	
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	AH	Moore et al., Incidence, causes, and treatment of iron deficiency anemia in hemodialysis patients, <u>J. Renal. Nutrition</u> , 2:105-112 (1992).	
	AI	Kleiner et al., The role of iron and other factors in patients unresponsive to erythropoietin therapy, <u>Seminars in Dialysis</u> , 8:(1):29-34 (1995).	
	AJ	Konopka et al., Iron transfer from transferrin ot ferritin mediated by polyphosphate compounds, <u>Biochem. Biophys. Acta.</u> , 677:417-423 (1981).	
	AK	Konopka et al., Iron transfer from transferrin ot ferritin mediated by polyphosphate compounds, <u>Biochem. Biophys. Acta.</u> , 96(3):1408-1413 (1980).	
	AL	Morgan, Iron exchange between transferrin molecules mediated by phosphate compounds and other cell metabolites, <u>Biochem. Biophys. Acta.</u> , 499(1):169-177 (1977).	
	AM	Kolff, First clinical experience with artificial kidney, <u>Ann. Intern. Med.</u> , 62:608 (1965).	
	AN	Scribner et al., The treatment of chronic uremia by means of intermittent hemodialysis; a preliminary report, <u>Trans. Amer. Soc. Artif. Int. Organs.</u> , 6:114 (1960).	
	AO	Jacobs et al., Isolation and characterization of genomic and cDNA clones of human erythropoietin, <u>Nature</u> , 313:806-810 (1985),	
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	AP	Levin, The impact of epoetin alfa: quality of life and hematocrit level, <u>Am. J. Kid. Dis.</u> , XX (Su;;l. 1 (July):16-20 (1992).	
	AQ	Eschbach et al., Iron balance in hemodialysis patients, <u>Ann. Intern. Med.</u> , 87:710-713 (1977).	
	AR	Woorwood, Blood Rev., 4:259-269 (1980).	
	AS	Macdougall et al., Detection of functional iron deficiency during erythropoietin treatment: a new approach, <u>Br. Med. J.</u> , 304:225-226 (1992).	
	AT	Van Wyck et al., Iron status in patients reciving erythropoietin for dialysis-associated anemia, <u>Kidney Int.</u> , 35:712-716 (1989).	
	AU	Wingard et al., Efficacy of oral iron therapy inpatients receiving recombinant human erythropoietin, <u>Am. J. Kid. Dis.</u> , 25:433-439 (1995).	
	AV	MacDougall et al., Poor response to the treatment of renal anaemia with erythropoietin corrected iron..., <u>Br. Med. J.</u> , 299:157-158 (1989).	
	AW	Schaeffer and Schaefer, The hypochromic red cell: a new parameter for monitoring or iron supplementation, <u>J. Perinat. Med.</u> , 23:83-88 (1995).	
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	AX	Horl, How to diagnose and correct iron deficiency during r-huEPO therapy-a consensus report, <u>Nephrol. Dial. Transplant.</u> , 11:246-250 (1996).	
	AY	Sepandj et al., Econommic appraisal of maintenance parenteral iron administration in treatment of anaemia in chronic..., <u>Nephrol. Dial. Transplant.</u> , 11:319-322 (1996).	
	AZ	Rosenlof et al., Iron availability is transiently improved by intravenous iron medication in patients..., <u>Clin. Nephrol.</u> , 43:249-255 (1995).	
	BA	Fishbane and Lynn, The utility of zinc protoporphyrin for predicting the need for intravenous iron therapy..., <u>Am. J. Kidney Dis.</u> , 25:426-432 (1995).	
	BB	Macdougall et al., A randomized controlled study of iron supplementation in patients treated with erythropoietin, <u>J. Amer. Soc. Nephrol.</u> , 4:428 (abstract) (1993).	
	BC	Sunder-Plassmann and Horl., Importance of iron supply for erythropoietin therapy, <u>Nephrol. Dial. Transplant.</u> , 10:2070-2076 (1995).	
	BD	Schaeffer and Schaeffer, Management of iron substitution therapy during r-HuEPO therapy in chronic renal failure patients, <u>Erythropoiesis</u> , 3:71-75 (1992).	
	BE	Nyvad et al., Intravenous iron-sucrose complex to reduce epoetin demand in dialysis patients, <u>Lancet</u> , 344:1305-1306 (1994).	
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	BD	Hamstra et al., Intravenous iron dextran in clinical medicine, JAMA, 243:1726-1731 (1980).	
	BE	Kumpf and Holland, Parenteral iron dextran therapy, DICP Ann Pharmacother, 24:162-166 (1990).	
	BF	Weinberg, Iron withholding: a defense against infection and neoplasia, Physiol. Rev., 64-65-102 (1984).	
	BG	Heath et al., Quantitative aspects of iron deficiency in hypochromic anemia, J. Clin. Invest., 11:1293 (1932).	
	BH	Best and Taylor, The Physiological Basis of Medical Practice, The Williams & Wilkins Co., Baltimore, MD pp. 94-99 (1943).	
	BI	Nissim, Intravenous administration of iron, Lancet, 2:49-51 (1947).	
	BJ	Goetsch et al., Observations on the effect of massive doses of iron given intravenously to patients with hypochromic anemia (1946).	
	BK	Cox et al., Valency investigations of iron dextran ('Imferon'), Nature, 207:1202-1203 (1965).	
	BL	Goldberg, In Iron in Clinical Medicine, eds. Wallerstein, Ro Mettier, SR. Berkeley: Univ. of California Press, Vol. 78 (1958).	
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	BM	Hatton et al., Removal of iron dextran by hemodialysis: as in vitro study, Am. J. Kid. Dis., 26(2):327-330 (1995).	
	BN	Pascual et al., Intravenous Fe-Gluconate-Na for iron-deficient patients on hemodialysis, Nephron, 60:121 (1992).	
	BO	Allegra et al., Iron deficiency in maintenance hemodialysis patients: assessment of diagnosis criteria..., Nephron, 57:175-182 (1991).	
	BP	Pollack and Weaver, Guinea pig and human red cell hemolysates release iron from transferrin, J. Lab. Clin. Med., 105(5):629-634 (1985).	
	BQ	Pollack et al., Iron removal from transferrin. An experimental study., Biochim. Biophys. Acta., 497(2):481-487 (1977).	
	BR	Morgan, Studies on the mechanism of iron release from transferrin, Biochim. Biophys. Acta., 580(2):312-326 (1979).	
	BS	Carver and Frieden, Factors affecting the adenosine triphosphate induced release of iron from transferrin, Biochemistry, 17(1):167-172 (1978).	
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	BT	Nilsen and Romslo, Phrophosphate as a ligand for delivery of iron to isolated rat-liver mitochondria, <u>Biochim. Biophys. Acta.</u> , 766(1):233-239 (1984).	
	BU	Javiad et al., Interactions between infections, malnutrition and iron nutritional status in Pakistani infants..., <u>Acta. Paeditrica Scandinavica - Supplement</u> , 374:141-50 (1991).	
	BV	Byrd and Horwitz, Lactoferrin inhibits or promotes Legionella pneumopilla intracellular multiplication..., <u>J. Clin. Invest.</u> , 88(4):1103-1112 (1991).	
	BW	Ristroph et al., Chemically defined medium for Legionella pneumophila growth, <u>J. Clin. Microbiology</u> , 13(1):115-119 (1981).	
	BX	Feeley et al., Primary isolation media for Legionnaires disease bacterium, <u>Journal of Clinical Microbiology</u> , 8(3):320-5 (1978).	
	BY	Maurer et al., Paramagnetic pyrophosphate. Preliminary studies on magnetic resonance contrast enhancement of acute myocardial..., <u>Investigative Radiology</u> , 25(2):153-63 (1990).	
	BZ	Stevenson et al., The toxicity of Sn-pyrophosphate: clinical manifestations prior to acute LD50, <u>J. Nucl. Med.</u> , 15:252-256 (1974).	
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	CA	Harken et al., Early ischemia after complete coronary ligation in the rabbit, dog, pig and monkey, Am. J. Physiol., 241:H202 (1981).	
	CB	Sillen and Martell, Stability constants of metal-ion complexes, The Chemical Society, London, (select pages only) (1964).	
	CD	Kornberg, On the metabolic significance of phosphorolytic and pyrophosphorolytic reactions, In Kasha M, Pullman B, eds. <u>Horizons on Biochemistry</u> , New York, Academic Press, pp. 251-264 (1962).	
	CE	Jung et al., The fate of intravenously injected 32-p-pyrophosphate in dogs, Amer. J. Physiol., 218:1757 (1970).	
	CF	Fleisch and Bisaz, Mechanism of calcification: inhibitory role of pyrophosphate, Nature (Lond.), 195:911 (1962).	
	CG	Fleisch, in Fleisch H, ed., <u>Bisphosphonates in bone disease: from the laboratory to the patient</u> , 2 nd ed. Carnforth, Lancs, England: The Parthenon Publishing Group Ltd., pp. 31-33 (1995).	
	CH	U.S. Renal Data System, USRDS 1995 Annual Data Report., The National Institutes of Health, National Institute of Diabetes and digestive and Kidney Diseases, Bethesda, MD (1995).	
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	CI	Ifudo et al., The intensity of hemodialysis and the response to rerythropoietin in patients with end stage renal disease, <u>N. Engl. J. Med.</u> , 334:420-425 (1996).	
	CJ	Cheuk et al., Kinetics of pyrophosphate induced iron release from fiferic ovotranferrin, <u>J. of Inorganic Biochemistry</u> , 29:301-311 (1987).	
	CK	Fishbane et al., Reduction in recombinant human erythropoietin doses by the use of chronic intravenous iron supplementation, <u>Am. J. Kidney Diseases</u> , 26:41-46 (1995).	
	CL	Hurrett et al., Iron fortification of infant cerals: a proposal for the use of ferrous fumarate..., <u>Am. J. Clin. Nutr.</u> , 49:1274-82 (1989).	
	CM	Moore, An outline of iron metabolism, pp. 5-7 (only information available).	
	CN	Nilsen, Effects pf calcium on hepatocyte iron uptake from tranferrin iron-pyrophosphate and iron-ascorbate. (only information available; best copy).	
	CO	Schibler, Inhibition by pyrophosphate and poly-phosphate of aortic calcification induced by vitamin D, in rats, <u>J. Clin. Sci.</u> , 35:363-372 (1968).	
	CP	Tsuji et al., <u>Eur. J. Surg.</u> 161:29-33 (1995)	
	CQ	Starkenstein, E., Beitrage zur Pharmakologie des Eisens., Archiv fur experiment, <u>Path. u. Pharmakol.</u> 118:131-191 (1921)	
EXAMINER SIGNATURE		DATE CONSIDERED	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.